

Office Action Summary	Application No. 10/593,259	Applicant(s) KRANICH ET AL.	
	Examiner JEAN CORNET	Art Unit 1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 11-19 is/are pending in the application.
- 5a) Of the above claim(s) 14-16 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 11-13 and 17-19 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date <u>PTO-413B</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/16/2011 has been entered.

Interview

2. It is noted that Applicant amended the claims to include the compound claims 17-19, which were originally presented as the use claims of formulae (Ia) and (Ib). Said use claims were interpreted as a compound claim, method of preparing and method of treating. However since during the interview of August 10, 2011, the Examiner stated he would consider rejoining the compound claims once the pharmaceutical composition claims are found allowable, the compound claims originally from Group (III), which were previously withdrawn are now rejoined although the composition claims are not allowable. Therefore, claims 11-13 and 17-19 are under examination.

Rejection Maintained but modified to address new claims 17-19.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

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is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

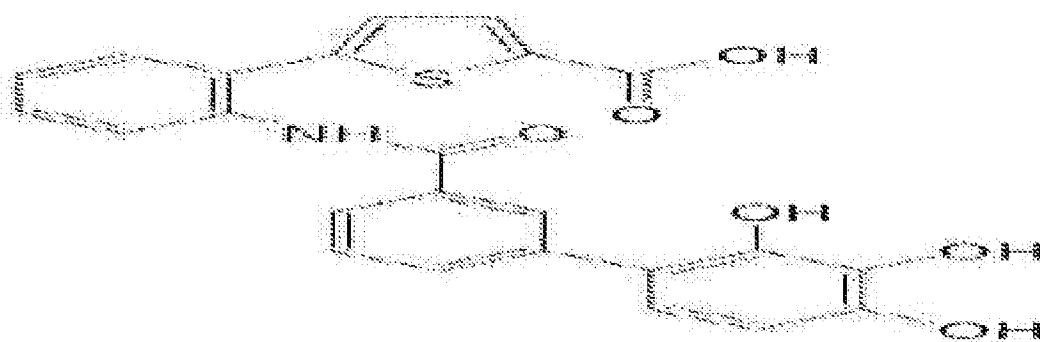
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-13 with the addition of new claims 17-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-6 of US patent 7,919,532. Although the conflicting claims are not identical, they are not patentably distinct from each other. Both the instant and the US patent are drawn to a composition comprising a triply hydroxylated phenyl ring core. The variable subgroups of both the instant and the US patent overlap. The compounds of the instant and the US patent are positional isomers and are, thus, considered obvious variants of each other. "Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH₂- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties." *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977). See also *In re May*, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978) (stereoisomers *prima facie* obvious) (MPEP § 2144.09(II)).

Affidavits

Receipt of the aforementioned Affidavit is acknowledged and has been entered. The Declaration of Dr. Kranich argues that the compounds of the instant application comprising 2, 3, 4-hydroxy substituted phenyl compound or 3, 4, 5-trihydroxy substituted phenyl compound lead to unexpected technical effects compared to the compounds of the US patent encompass a 2, 4, 6-trihydroxy phenyl ring substituted. The experimental test results clearly demonstrate that the 2, 3, 4-hydroxy substituted phenyl and the 3, 4, 5-trihydroxy substituted phenyl compounds have a higher normalized inhibition of either E- and P-selectin than the 2, 4, 6-trihydroxy phenyl compounds of the US patent. In response, it is noted that the Declaration only 2, 3, 4-hydroxy substituted phenyl compounds (formula D) were tested and compared with the 2, 4, 6-trihydroxy phenyl compounds of the US patent. No comparison was made between the 3, 4, 5-trihydroxy substituted phenyl compounds of the formula C and the compound of the formula (I) of the US patent. Additionally, the unexpected technical effect Applicant argues about is not unexpected over the compound of the US patent. For instance, Table 1 of the Declaration shows the inhibition ratio of (i), i.e. E-selectin for the compound of example 48 of the instant application is 1.4, whereas the ratio for the compound of example 63 of the US patent in comparison is 1.2. Such result does not really show a great difference in inhibition ratio for E-selectin. However, although this compound of the instant application with the following structure:

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shows a ratio of E-selectin of 2.0 and P-selectin of 2.6 in comparison with the compound of example 26 of the US patent showing a ratio of E-selectin of 1.1, and P-selectin of 0.8, there does not appear to "a marked improvement" to be classified as a difference in kind in E-selectin ratio for compound having this structure of the instant application



Is 1.4 and P-selectin ratio of 1.5, whereas the ratio for the compound of example 60 of the US patent in comparison is 1.0 for both P-selectin and E-selectin. MPEP 716.02 states "In re Waymouth, 499 F.2d 1273, 1276, 182 USPQ 290, 293 (CCPA 1974), the court held that unexpected results for a claimed range as compared with the range disclosed in the prior art had been shown by a demonstration of "a marked improvement, over the results achieved under other ratios, as to be classified as a difference in kind, rather than one of degree." Compare In re Wagner, 371 F.2d 877, 884, 152 USPQ 552, 560 (CCPA 1967) (differences in properties cannot be disregarded on the ground they are differences in degree rather than in kind); Ex parte Gelles,

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22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992) (“we generally consider a discussion of results in terms of differences in degree’ as compared to differences in kind’ . . . to have very little meaning in a relevant legal sense”. In the present case, it is clear from the Declaration that some compounds that fall within the scope of formula (D) of the instant application and some compounds that fall within the scope of the formula (I) of the US patent exhibit similar properties as they are isomers of each other. Therefore the rejection of record is maintained.

Applicant's argument is the same as above. Same response to the Declaration applies to Applicant's argument.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEAN CORNET whose telephone number is (571)270-7669. The examiner can normally be reached on Monday-Thursday 7.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JC/

/Brandon J Fetterolf/

Supervisory Patent Examiner, Art Unit 1628